

JCS18 U.S. PTO
09/177502
10/23/98

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Slater)
)
v.) INTERFERENCE NO. 103,765
)
Rydell) Administrative Patent Judge Pate

DECLARATION OF JOSEPH A. O'BRIEN

I, Joseph A. O'Brien, declare and say as follows:

1. That between the fall of 1990 and 1994, I was employed by Everest Medical Corporation and was a co-worker with Mark A. Rydell and David J. Parins at this company. My title at that time was "Marketing -Product Manager" and, in this capacity, I frequently met with medical professionals to obtain information on what problems were being encountered and what improvements ought to be made to existing electrosurgical instruments. I would then discuss such needs with Everest Medical development personnel, principally Mark A. Rydell and David J. Parins, whom I found to be exceptionally skilled at devising and constructing working prototypes of such devices.

2. In December, 1991, I became aware that Mark Rydell had assembled an electrosurgical hook scissors. It comprised an elongated, tubular, metal barrel covered with a black plastic insulating sleeve. At its proximal end was a scissors handle assembly molded from a white plastic material and that included a stationary scissors-style handle and pivotally secured to the

stationary handle was a movable handle. These handle parts included finger loops to facilitate grasping, opening and closing of the movable handle relative to the stationary one. Affixed to the distal end of the tubular metal barrel was a fixed (immovable) metal scissors blade support member. A flat piece of black insulating plastic was bonded to the metal blade support and bonded to the other side of the plastic insulator was a thin sheet of stainless steel that defined a cutting edge and a shearing surface. Pivotally attached to the blade support was a movable hook-shaped metal cutting blade. A push-rod passing through the tubular metal barrel was used to join the movable handle to the movable hook-shaped cutting blade, such that when the handle parts were opened and closed, the movable scissors hook blade would likewise move opened and closed relative to the fixed composite blade comprising the blade support, insulating plastic layer and the thin sheet of stainless steel. The push rod was metal and it was covered by a plastic sheath to prevent it from shorting electrically to the inside metal wall of the tubular barrel. Provision was made for electrically connecting the push-rod to one terminal of an electrosurgical generator and the metal barrel to its other terminal, such that a voltage could be applied between the metal blade support of the fixed blade member and the movable blade.

3. I have reviewed the Declaration of Mark A. Rydell dated 9/30, 1998, and recognize the photograph comprising Exhibit F to the Declaration as the prototype scissors which Mr.

Rydell constructed in December 1991, and which is described in Paragraph 2 hereof.

4. On several occasions in December, 1991, I actually used the above-described scissors to cut and coagulate animal tissue. First, in the Everest Development Lab, I used it to snip through a piece of steak, which, as I recall, was about 1/4 in. thick. I used the scissors to cut, both with and without electrical power applied. With power applied, noticeable desiccation and searing of the meat adjacent the borders of the cut occurred. Mr. Rydell not only demonstrated and allowed me to use the device, but other coworkers at Everest, as well, were invited to observe its use. This testing at Everest Medical Corporation occurred prior to December 19, 1991.

5. On December 17, 1991, we received a call from Myra Urnas who worked at the Animal Laboratory associated with the Medical School at the University of Minnesota. She indicated that a live animal (a dog) would be operated upon by surgeons at the U of M on December 19, 1991, and indicated that the animal would be available to us for use in evaluating instruments under development at Everest Medical before the animal was sacrificed. This accommodation with the U of M had been worked out earlier and the December 19, 1991 episode was not the first occasion where Everest personnel were allowed to avail themselves of the facilities at the U of M Animal Laboratory. On December 19, 1991, I, along with Mark Rydell, drove over to the U of M Animal Laboratory at the appointed time for the purpose of testing three

different instruments, including the electrosurgical scissors described in paragraph 2 hereof and depicted in Exhibit F of the Declaration of Mark A. Rydell dated 9/30, 1998.

6. The testing of the hook scissors described above in paragraph 2 hereof lasted for a period of 20-30 minutes. Both Mark Rydell and I used the scissors to cut various different tissue types and blood vessels of different sizes, both with and without electrical power applied to the scissors. The scissors was operated in its normally intended fashion in a living animal and we were able to both mechanically cut and electrically coagulate cut blood vessels by applying a RF voltage between the movable hook blade and the stationary blade support.

Our testing also included varying the power level of the electrosurgical generator to note the effect that that had on the ability of the scissors to coagulate tissue. Based upon the testing conducted on the hook scissors described in paragraph 2 hereof on December 19, 1991, we concluded that the scissors worked well in coagulating cut, bleeding blood vessels to promote hemostasis but that the mechanical cutting ability of the prototype model under test was not on a par with conventional laparoscopic scissors.

7. Attached hereto as Exhibit 1 is an interoffice memo which I wrote on or about Tuesday, December 17, 1991. On page 2 of that memo, I mentioned that two designs of a bipolar laparoscopic scissors are to be used in the dog lab at the U of M on Thursday. This memo refreshes my recollection that the

testing of the hook scissors did, in fact, take place on December 19, 1991.

8. Attached hereto as Exhibit 2 is an interoffice memo reporting on a product development meeting held December 23, 1991. On page 2 thereof it refers to the fact that the results of the testing done at the U of M Animal Laboratory on December 19, 1991, were reviewed with the attendees of the product development meeting, further confirming my recollection that the testing mentioned in paragraph 5 hereof did, in fact, occur on December 19, 1991. The statement, "Good coagulation but poor mechanical cut", summarized the conclusions which Mark Rydell and I arrived at following the December 19, 1991 testing of the hook scissors described in paragraph 2 hereof at the U of M Animal Laboratory.

9. I have carefully read the Declaration of Mark A. Rydell dated 9/30, 1998, and the exhibits referenced therein, and I find the facts set forth therein are entirely consistent with my recollections concerning the constructional features and testing of the hook scissors described in paragraph 2 hereof.

10. I hereby state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may

jeopardize the validity of the above application or any patent
issuing thereon.

Further affiant saith not.

Dated: 9/30, 1998.



Joseph A. O'Brien

Exhibit 1



Everest Medical

INTEROFFICE MEMO

TO: Mike H, Steve H, Mark R, Dave P, Jerry S, Greg G,
Brent A, Kevin R.

FROM: Joe O.

SUBJECT: New Product Meeting of 12/17/91 12/19/21

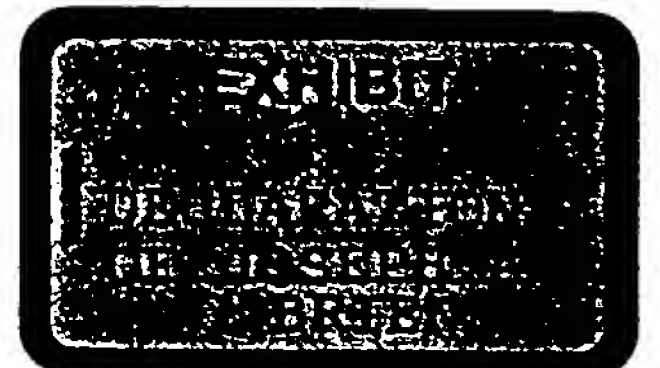
The following is a proposed list of priorities to be agreed upon on 12/23/91. Please review for that meeting. Thanks!

NEW PRODUCT PRIORITIES

1. Bipolar Laparoscopic Scissors
2. Bipolar Laparoscopic Forceps
3. Suction/Irrigation handle for BiLAP
4. Reusable BiLAP with interchangeable tips
5. Adapter Box for BiLAP to competitive generators
6. Traditional design endoscopic bipolar biopsy device
7. Fulgurating Snare
8. Monopolar Snare

PRODUCT MODIFICATION PRIORITIES

1. BiLAP Modifications; Ceramic Tip / Detent / Stiffer Tubing
2. Hand Switching Straight Tip BiLAP
3. BiLAP Modifications; Steam Autoclavable / 4.8 mm
4. BiTOME
5. ERCP
6. Non Stick Tip for BiCOAG Probe
7. BiBx



Bipolar Laparoscopic Scissors:

- 2 designs to be used in dog lab at U of M on Thursday. 2 variations of coated design to be tried.
- Joe, Mark and Greg to review and update gannt chart before end of the week.
- Joe to complete marketing spec. by end of week.
- Design to review and discuss with marketing the various options for making the device with a steam autoclavable materials.

Bipolar Laparoscopic Forceps:

- Joe will get notes from Kevin and write up uses to date for distribution by end of week.
- Joe, Mark and Greg to review and update gannt chart by end of week.
- Joe to finish marketing spec. by end of week.

BiLap Modifications: Ceramic Tip / Detent / Stiffer Tubing:

- Ceramic Tips will be in house on Jan. 16th
- Stiffer Tubing should be in house next week, by Christmas.
- Detent: Kevin is to determine immediately whether to build mold at an estimated cost of \$7500.00.

Suction / Irrigation Handle:

- Kevin is to complete marketing spec. and update gannt chart.
- Steve has potential designers in Ct. and Mi., he will get with Kevin and have a plan by next week.
- Corey will begin drawing potential designs for FS trumpet valve.

Hand Switching Straight Tip:

- Kevin will prepare or draft marketing spec. and gannt chart by next week.

New Product Meeting
Page 3

ERCP

- Joe will speak to Ted about guidewire issue, decision by next week.

Adapter Boxes:

- Resolve competitive generator issues for certain as soon as possible. Some testing will be done at the lab on Thursday.
- Greg agreed to call Amprea and get a definite date by next week.

Miscellaneous:

- Kevin will contact Marlow/Dexide and find a way to purchase irrigation sets for use with the BiLAP as soon as possible.
- Confusion remains re. custom BiTOME order from Japan. Joe will resolve by next week.

Exhibit 2



Everest Medical

INTEROFFICE MEMO

TO: Mike H, Steve H, Mark R, Jerry S, Dave P, Greg G,
Brent A, Kevin R

FROM: Joe O'B

SUBJECT: Product Development Meeting 12/23

The following list of development priorities was reviewed and agreed upon. It will be posted and included in the weekly product development meeting notes.

NEW PRODUCTS PRIORITIES

1. Bipolar Laparoscopic Scissors
2. Bipolar Laparoscopic Forceps
3. Suction/Irrigation Handle for BiLAP
4. Reusable BiLAP with interchangeable tips
5. Adapter box for competitive generators
6. Traditional design endoscopic biopsy device
7. Fulgurating Snare
8. Monopolar Snare

PRODUCT MODIFICATION PRIORITIES

- 5128
1. BiLAP modifications: ceramic tip / detent / stiffer tubing / non-stick coating
 2. Model 5126 BiSNARE
 3. Hand switching straight tip BiLAP
 4. BiLAP modifications: Steam autoclavable / 4.8 mm
 5. BiTOME



6. ERCP
7. Non-Stick coating for BiCOAG PROBE
8. BiBx

Bipolar Laparoscopic Scissors:

- Marketing specification completed
- Reviewed GANTT chart prior to meeting (Mark, Greg, Joe) and will revise and distribute. Product introduction is scheduled for April 10th.
- Joe will review revised GANTT chart with Manufacturing by end of week.
- Results of dog lab were reviewed. Good coagulation but poor mechanical cut.
- Mark will have new prototype as well as blade and handle drawings by Jan. 7.
- Dog lab should be scheduled to test new prototype.

Bipolar Laparoscopic Forceps:

- Marketing Specification completed
- Reviewed GANTT chart prior to meeting (Mark, Greg, Joe) and will revise and distribute. Product introduction scheduled for April 10th.
- Joe will review revised GANTT chart with manufacturing this week.
- Memo describing uses to date has been distributed.
- Mark is building a second unit. More uses will be scheduled.

BiLAP Modifications: Ceramic Tip / Detent / Stiffer Tubing / Coating:

- Ceramic tips will be in house on Jan. 16th.
- According to Greg, stiffer tubing was improperly processed by Jerneen. New tubing will be in house next week. Some testing can start on the tubing we have.
- Detent; ten devices will be built by next week.
- Coating; two coatings have been initially evaluated with unspectacular results. Greg will evaluate 3M, Videx and gold for their potential.

Suction / Irrigation Handle:

- Kevin needs to complete marketing spec immediately. In connection with the marketing spec., Kevin should discuss prototype and GANTT chart with Design.
- Steve will follow up w/ Kevin on potential outside design.
- Corey will begin drawing potential designs.

Hand switching straight tip:

- Kevin needs to develop or revise a marketing spec. and GANTT chart for the hand switching straight tip.
- Kevin and Steve need to address the need for hand switching J, L and H per design request.

Adapter Box:

- Greg said that the first box will be here Thursday 12/26. The box needs to be tested as soon as possible.

Miscellaneous:

- Marketing will get access to an Olympus video system to evaluate interference with our monopolar generator.
- Joe will submit second communication re. Japanese special BiTOME's.